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Customer No.: 07278

Docket No.: 05432/100M919-US1

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Connie Sanchez, et al.

Serial No.: 10/644,579

Art Unit: 1614

Filed: August 20, 2003

Examiner: Not Yet Assigned

For: **THE USE OF ENANTIOMERIC PURE ESCITALOPRAM**

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

In order to comply with 37 CFR 1.97 and 1.98, attached hereto is a copy of form PTO/SB/08 and a copies of the documents listed thereon. The U.S. patents cited in the attached form PTO/SB/08 are not supplied pursuant to a notice of waiver of the requirement under 37 CFR 1.98(a)(2)(i) by the U.S. Patent and Trademark Office dated June 30, 2003.

In accordance with MPEP Sections 609 and 707.05(b), it is requested that each document cited be given thorough consideration and that it be cited of record in the prosecution history of the present application by initialing form PTO/SB/08 next to the document. Such initialing is requested even if the Examiner does not consider a cited document to be sufficiently pertinent to use in a rejection, or otherwise does not consider it to be prior art for

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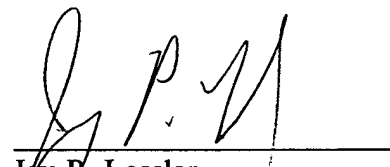
any reason, or even if the Examiner does not believe that the guidelines for citation have been fully complied with. This is requested so that each document becomes listed on the face of the patent issuing on the present application.

The present Information Disclosure Statement is being submitted in compliance with 37 CFR 1.56, but the citation of such document is not to be construed as an admission that such document is necessarily relevant or prior art. No representation is intended that the cited documents represent the results of a complete search, and it is anticipated that the Examiner, in the normal course of examination, will make an independent search and will determine the best prior art consistent with 37 CFR 1.104(a) and in the course of each search, will review for relevance every document cited on the attached form even if not initialed.

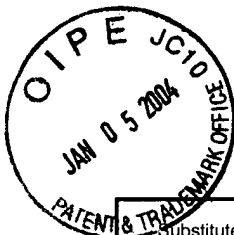
This submission is filed before the mailing date of a first Office action on the merits. It is believed that no fee is due. However, if the Commissioner determines that a fee is due, the Commissioner is hereby authorized to charge Deposit Account No. 04-0100 for any deficiency up to \$2500.00.

Early and favorable consideration is earnestly solicited.

Respectfully submitted,

  
\_\_\_\_\_  
Jay P. Lessler  
Registration No. 41,151  
Attorney for Applicant(s)

DARBY & DARBY  
Post Office Box 5257  
New York, NY 10150-5257  
(212) 527-7700



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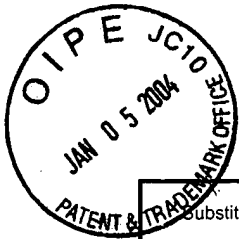
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<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/644,579
				Filing Date	August 20, 2003
				First Named Inventor	Connie Sanchez
				Art Unit	N/A
				Examiner Name	Not Yet Assigned
Sheet	1	of	3	Attorney Docket Number	05432/100M919-US1

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	1.	US-6,469,064 B2	10-22-2002	Druzgala	
	2.	US-6,333,357 B1	12-25-2001	Eig	
	3.	US-6,159,971	12-12-2000	Berg et al.	
	4.	US-6,147,072	11-14-2000	Bymaster et al.	
	5.	US-6,069,177	05-30-2000	Carlier et al.	
	6.	US-5,962,514	10-05-1999	Evenden et al.	
	7.	US-5,958,429	09-28-1999	Wong	
	8.	US-5,788,986	08-04-1998	Dodman	
	9.	US-5,648,396	07-15-1997	Young et al.	
	10.	US-5,296,507	03-22-1994	Tanaka et al.	
	11.	US-5,114,976	05-19-1992	Norden	
	12.	US-4,962,128	10-09-1990	Doogen et al.	
	13.	US-4,943,590	07-24-1990	Boegesoe et al.	
	14.	US-4,902,710	02-20-1990	Foster et al.	
	15.	US-4,650,884	01-23-1979	Bogeso et al.	
	16.	US-4,136,193	01-23-1979	Bogeso et al.	
	17.	US-3,467,675	09-16-1969	Peterson et al.	
	18.	US-Re. 34712	08-30-1994	Boegesoe et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	19.	EP-0 347 066 A1	12-20-1989	H. Lundbeck A/S		
	20.	WO-01/03694 A1	01-18-2001	H. Lundbeck A/S		
	21.	WO-00/15220	03-23-2000	Astra Aktiebolag		
	22.	WO-01/54681 A2	08-02-2001	Massachusetts Institute of Technology		
	23.	WO-00/15219	03-23-2000	Astra Aktiebolag		
	24.	WO-00/03701	01-27-2000	Massachusetts Institute of Technology		
	25.	WO-00/02551	01-20-2000	NPS Pharmaceutical, Inc.		
	26.	EP-0759299	02-26-1997	Eli Lilly and Company		
	27.	EP-0714663 A2	06-05-1996	Eli Lilly and Company		
	28.	WO-93/09769	05-27-1993	Sepracor, Inc.		
	29.	WO-92/18005	10-29-1992	National Institutes of Health		
	30.	WO-00/34263	06-15-2000	H. Lundbeck A/S		
	31.	EP-0474580	03-11-1992	H. Lundbeck A/S		

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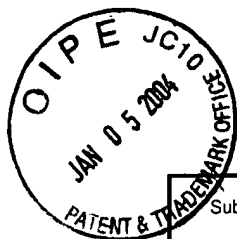
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NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	32.	Kornstein, S.C. and Schneider, R.K., Clinical features of treatment-resistant depression, J. Clin. Psychiatr 2001, 62 Suppl 16, 18-25		
	33.	Nierenberg, A.A and DeCecco, L.M., Definitions of antidepressant treatment response, remission, non-response, partial response, and other relevant outcomes: A focus on treatment-resistant depression, J. Clin. Psychiatr 2001, 62 Suppl 16, 5-9		
	34.	Sackeim, H.A., The definition and meaning of treatment-resistant depression, J. Clin. Psychiatr 2001, 62 Suppl 16, 10-17		
	35.	Willner, P., Psychopharmacology, 1997, 134, 319-329		
	36.	A.F. Joubert et al., "Citalopram and Anxiety Disorders," Rev. Contemp. Pharmacother 10: 79-131 (1999)		
	37.	Ulla M. Lepola et al., "A Controlled Perspective, 1-Year Trial of Citalopram in the Treatment of Panic Disorder," J. Clin. Psychiatry 59, 10: 528-534 (1998)		
	38.	H. Koponen et al., "Citalopram in the treatment of obsessive-compulsive disorder: an open pilot study," Acta Psychiatrica Scandinavica 96:343-346 (1997)		
	39.	Dan J. Stein et al., "Use of serotonin selective reuptake inhibitor citalopram in obsessive-compulsive disorder," Journal of Serotonin Research 1: 29-33 (1996)		
	40.	Bigler, Allan et al., "Quantitative Structure-activity Relationships in a Series of Selective 5-HT uptake inhibitors," Eur. J. Med. Chem. 3:289-295 (1997)		
	41.	Soraya Seedat et al., "Open Trial of Citalopram in adults with post-traumatic stress disorder," International Journal of Neuropsychopharmacology 3: 135-140 (2000)		
	42.	Ihoko Muraki et al., "Effect of subchronic lithium carbonate treatment on anxiolytic-like effect of citalopram and MKC-242 in conditioned fear stress in the rat," European Journal of Pharmacology 383:223-229 (1999)		
	43.	Jennifer Y. Tan et al, "Citalopram in the Treatment of Depression and Other Potential Uses in Psychiatry," Pharmacotherapy 19, 6: 675-689 (1999)		
	44.	Mario Amore et al., "Short-term and Long-term evaluation of Selective Serotonin Reuptake Inhibitors in the Treatment of Panic Disorder: Fluoxetine vs. Citalopram," Hum. Psychopharmacol. Clin. Exp. 14: 435-440 (1999)		
	45.	Emanuela Mundo, M.D. et al., "Efficacy of Fluvoxamine, Paroxetine, and Citalopram in the Treatment of Obsessive-Compulsive Disorder: A Single-Blind Study," Journal of Clinical Psychopharmacology 17, 4: 267-271 (August 1997)		
	46.	Zoltan Rihmer, "Successful treatment of salbutamol-induced panic disorder with citalopram," European Neuropsychopharmacology 7:241-242 (1997)		
	47.	Takeshi Inoue et al., "Effect of citalopram, a selective serotonin reuptake inhibitor, on the acquisition of conditioned freezing," European Journal of Pharmacology 311: 1-6 (1996)		

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Sheet	3	of	3	Attorney Docket Number	05432/100M919-US1

48.	U. Lepola et al., "Citalopram in the Treatment of Early-onset Panic Disorder and School Phobia," Pharmacopsychiatry 29: 30-32 (January 1996)	
49.	J. Hyttel et al., "The Pharmacology of Citalopram," Rev. Contemp. Pharmacother. 6: 271-285 (1995)	
50.	American Psychiatric Associations, "DSM-IV" (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition): 393-444 (1994)	
51.	Hytell, J., Prog. Neuro-Psychopharmacol. & Biol. Psychiat., 1982, 6, 277-295	
52.	Gravem, A., Acta Psychiatr. Scand., 1987, 75, 478-486	
53.	Sanchez, C., Effect of serotonergic drugs on footshock-induced ultrasonic vocalization in adult male rats, Behav. Pharmacol. 1993; 4:267-277	
54.	Sanchez, C., Pharmacol. Toxicol. 77, 71-78 (1995)	
55.	Sanchez, C., R-citalopram attenuates anxiolytic effects of escitalopram in a rat ultrasonic vocalisation model, European Journal of Pharmacology, 464, 2003, pp.155-158	
56.	Montgomery, S. et al., Escitalopram (S-Enantiomer of Citalopram): Clinical Efficacy and Onset of Action Predicted from a Rat Model, Pharmacology & Toxicology, 2001, 88, 282-286	
57.	Sanchez, C., Stress-induced vocalisation in adult animals: A valid model of anxiety?, European Journal of Pharmacology, 463 (2003) 133-143	
58.	Burke, W., et al., Fixed-Dose Trial of the Single Isomer SSRI Escitalopram in Depressed Outpatients, J. Clin Psychiatry, 63:4, April 2002	
59.	Wade, A., et al., Escitalopram 10 mg/day is effective and well tolerated in a placebo-controlled study in depression in primary care, International Clinical Psychopharmacology 2002, Vol. 17 No. 3	

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